

MINUTES OF MEETING

November 20, 1990

10:00 am

MPN, Room 201

Between: Division of OTC Drug Evaluation (HFD-210)

William Gilbertson
Gerald Rachanow
Jeanne Rippere

and McKenna, Conner & Cuneo
Marsha Gardner

Subject: Citizens Petition (CP 3, Docket No. 78N-0038) Filed on
Behalf of Haarmann & Reimer Corporation

McKenna, Conner & Cuneo filed a petition dated July 27, 1990 on behalf of Haarman & Reimer requesting that the agency (1) reopen the administrative record for OTC sunscreen drug products, (2) permit the filing of data on the use of the ingredient isoamyl-p-methoxycinnamate for consideration as a Category I (generally recognized safe and effective, and not misbranded) sunscreen active ingredient, and (3) permit the marketing in the United States of sunscreen formulations with isoamyl-p-methoxycinnamate during the OTC drug review process. Although isoamyl-p-methoxycinnamate has not been previously marketed in the United States, it has been sold extensively in Europe since 1976.

Ms. Gardner wished to discuss various aspects of the petition. We told her that we were still evaluating Haarman & Reimer's petition along with several other similar petitions concerning various sunscreen active ingredients with foreign marketing data instead of U. S. marketing data. She was particularly interested in the marketing status of products containing isoamyl-p-methoxycinnamate if the ingredient were accepted into the OTC drug review. We told her that even if the ingredient were accepted into the review, the agency would not be likely to permit the marketing of products containing the ingredient until the agency had evaluated the safety and efficacy data and published its tentative findings regarding the ingredient in the FEDERAL REGISTER. Such a publication would state whether the ingredient could be marketed at that time or not until after a period of time for public comment and publication of a final ruling regarding the ingredient.

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Ms. Gardner thanked us for our time, and the meeting ended.

Jeanne L. Rippere

cc: HFD-210:DDC-940.3/Reading/Deputy
HFD-213:(Sunscreens):Rippere
R/D:JRippere
F/T:WEGilbertson:GRachanow:JRippere:smp:11/26/90
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OK 12/3/90
W. M. T. 11/26/90
G.R. 12/3/90